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Hiroyuki Takada

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EXAMINER

RAMDHANIE, BOBBY

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,231	<b>Applicant(s)</b> TAKADA ET AL.	
	<b>Examiner</b> BOBBY RAMDHANIE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/15/2009 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed 06/15/2009 have been fully considered but they are not persuasive. The following reasons are why:

3. Applicants argue that Jenkins et al does not disclose the adhering liquid moving groove as recited in the instant Claims. Applicants also argue that "the projections 30, 36, 36' are finger-like members configured at the bottom of the container space and are not taught as having any function related to downward movement of a liquid (See Page 6 or Remarks)."

4. The Examiner would like to point out that Jenkins et al discloses that "As noted earlier, in accordance with the present invention each of the containers 10 carries an array of mutually spaced sonication improving projections 30. The individual projections 30 are spaced from each other to define channels 32 therebetween (See Column 4

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lines 26-30)" and "The spaces between the finger-like members 36, 36' define channels 32 which, as will be explained herein, **permit hydrating liquid flow into and through the recess 38**. It should be appreciated that the sonication improving **projections 30 may be disposed in any convenient orientation or at any convenient location within the container 10**. For example, if the finger-like members 36, 36' are used to define the projections 30, such members may be inclined with respect to the vertical axis of the container 10 and **may be mounted to the sidewalls 18A, 18B and/or the endwalls 20A, 20B** in addition to or in place of their mounting on the floor 24 (See Column 4 lines 40-52)."

5. The Examiner interprets these sections of Jenkins et al as support for the adhering liquid moving groove on the sidewall. These channels indeed facilitate movement of liquid into the container because during the process of sonication, the droplets that adhere to the channel (groove) in the confined space, form larger droplets within the small channel, and these larger droplets would rapidly be pulled by gravity into the container due to the force of gravity being larger than the force due to the droplet adhering to the sidewalls.

6. Applicants argue that Lee et al does not disclose the adhering liquid moving groove extending from the upper opening flush with the upper surface of the receptacle body to an intermediate position short of the bottom of the receptacle. Applicants argue that Lee et al, "teaches that reference numeral 86 is an "anti-wicking wall transition fillet" and a "key" feature of the cuvette" (column 5, lines 57-58). Lee et al teaches the anti-wicking wall transition fillet 86 that inhibits liquid moving to the bottom of the cuvette

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along an interior wall surface. **This teaching is opposite to the claimed groove that promotes downward movement of a liquid.** Lee et al teaches that the anti-wicking fillet 86 is designed to "completely minimize" capillary wicking so that cuvette washing may restore the used cuvette and "completely minimizes" liquid from moving to the bottom of the cuvette (see column 7, lines 7-25).” This section is copied from the Remarks filed on 06/15/2009, Page 6.

7. The Examiner respectfully disagrees with Applicants' interpretation of the Lee et al (US2005/0013746).

8. Lee et al (US2005/0013746), discloses the adhering liquid moving groove, and its function **is not “opposite to the claimed groove that promotes downward movement of a liquid.” Please see the following section for what Lee et al actually discloses (from [0057]):**

9. “... a key feature of the present invention is that the variable blend radius of curvature of anti-wicking wall transition fillets 86 (i.e. groove) increases as the location of the radius increases from the region of dashed line 87 **so that gravitational forces acting to attract capillary fluid towards the bottom surface 78 of cuvette 24 become greater than the surface tension forces that act to attract capillary fluid towards the top 82 of cuvette 24 thereby causing unwanted wicking to be essentially eliminated.**”

10. This section is interpreted as the groove of Lee et al, actually promotes the adhering liquid to move to the bottom of the cuvette and the gravitational forces upon the adhering liquid overcomes the surface tension forces that act to attract the fluid to

the top of the cuvette. **This is completely in agreement with the concept and function of the adhering liquid moving groove** of the Applicants' alleged invention.

11. The Lee et al patent (US7138091), discloses the same very concepts (See Column 6 line 65 to Column 7 line 17):

“It has been discovered that if the following relations are established between  $R_w$ ,  $R_x$ ,  $R_y$ , and  $R_z$ , then the amount of capillary wicking of fluids upwards along the interior surfaces of front wall 70, back wall, and side walls 74 and 76 of cuvette 24 is significantly minimized or totally eliminated:

(41) 1.  $R_w$  is essentially equal to  $R_x$ ; and,

(42) 2.  $R_y$  is generally greater than  $R_x$ ; and,

(43) 3.  $R_z$  is generally greater than  $R_y$ .

(44) When these relationships between the variable blend radii of curvature of anti-wicking fillets 86 at different heights of cuvette 24 are established, **capillary wicking of reagent residues from inside reaction cuvette 24 to an upper surface or outside surface has been found to so completely minimized** that cuvette washing by wash station 67 is capable of restoring a used cuvette to the general degree of cleanliness of an unused, new cuvette, and the integrity of reagent solutions is maintained so that accuracy of reaction assays performed therein is not adversely affected.”

12. This section of the Lee et al patent (US7138091) discloses the same concept and function of the US20050017346.

***Response to Amendment***

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 11-14, 16-18, 20-22, 24, & 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over HIRAMATSU ET AL in view of JENKINS ET AL (US4847050) or LEE ET AL (US20050013746).

4. Applicants claims are toward a device

5. Regarding Claims 11-14, 16-18, & 20-22, 24 & 25, HIRAMATSU ET AL discloses the cartridge, comprising: A). A receptacle body, including an upper surface; a plurality of wells formed in the receptacle body, the plurality of wells including: at least one storage well, including an upper opening flush with the upper surface of the receptacle body, and a closed bottom for containing a liquid, and at least one reaction well including; an upper opening flush with the upper surface of the receptacle body, a

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closed bottom for providing a reacting field; wherein a closure is attached to the upper surface of the receptacle body for closing at least the upper opening of the storage well, and wherein at least one of the storage well and the reaction well (See Figure 1 Items 21-29 & A-C). HIRAMATSU ET AL does not disclose that the reaction well includes an inner surface provided with an adhering liquid moving groove extending from the upper opening flush with the upper surface of the receptacle body to at an intermediate position short of the bottom of the receptacle body for downwardly moving the liquid which adheres on a peripheral portion of the upper opening of the well and on the closure by overcoming a surface tension of the adhering liquid.

6. JENKINS ET AL discloses a cartridge with A). At least one storage well including an upper opening and a closed bottom for containing a liquid (See Figure 1 Items 10 A-C); B). At least one reaction well including an upper opening and a closed bottom for providing a reacting field (See Figure 1 Items 10 A-C; and C). A closure for closing at least the upper opening of the storage well (See Column 2 lines 41-45, second sheet acts as a closure), wherein at least one of the storage well and the reaction well includes an inner surface wherein the inner wall provides an adhering liquid moving groove for downwardly moving the liquid which adheres on a peripheral portion of the upper opening of the well and on the closure by overcoming a surface tension of the adhering liquid (See Figure 3A-D & Column 4 line 58 to Column 5 line 37), and

7. LEE ET AL discloses the cartridge with A). At least one storage well including an upper opening and a closed bottom for containing a liquid (See Figure 5); B). At least one reaction well including an upper opening and a closed bottom for providing a



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reacting field (See Figure 8) and C). A closure for closing at least the upper opening of the storage well (See Figure 1 Item 26 & 28, both are storage areas which provide a closure to the opening of the storage well from the outside environment), wherein at least one of the storage well and the reaction well includes an inner surface wherein the inner wall provides an adhering liquid moving groove for downwardly moving the liquid which adheres on a peripheral portion of the upper opening of the well and on the closure by overcoming a surface tension of the adhering liquid (See Figure 8 Item 86). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wells of the cartridge of HIRAMATSU ET AL with the adhering liquid mover moving groove of either JENKINS ET AL or LEE ET AL and extend it from the upper opening and terminating at an intermediate position short of the closed bottom because according to both JENKINS ET AL and LEE ET AL, these grooves assist in guiding of the circulating hydrating liquid (See JENKINS ET AL Column 4 lines 53-56) and because LEE ET AL discloses these grooves inhibit liquid wicking along an interior wall surface (See Abstract and Field of Invention) and because Lee et al further discloses that these grooves are capable of restoring a used cuvette to the general degree of cleanliness of an unused, new cuvette, and the integrity of reagent solutions is maintained so that accuracy of reaction assays performed therein is not adversely affected (See [0052]). JENKINS ET AL also discloses the ability to position the grooves anywhere along the interior wall side (See Figure 2 Item 36 & See Column 4 lines 36-53).

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8. Additional Disclosures Included: Claim 12: Wherein the liquid comprises at least one of a reagent, a diluent, and a cleaning solution (See HIRAMATSU ET AL Abstract, [0059], [0104], and [0105]); Claim 13: Wherein the liquid comprises a reagent (See HIRAMATSU ET AL Abstract, [0059], [0104], and [0105]); Claim 14: Wherein the reagent is necessary, for causing immune reaction (See HIRAMATSU ET AL [0001], [0059], [0104], and [0105]); Claim 16: Wherein the closure comprises a sheet that contacts an upper end of the adhering liquid moving groove (See HIRAMATSU ET AL Figure 3 Item 31 in view of JENKINS ET AL or LEE ET AL, where the liquid adhering moving groove can be positioned at the top of the well or is integrated to be at the top of the well); Claim 17: Wherein there are a plurality of storage wells, the sheet collectively covering the upper openings of the storage wells (See Jenkins et al; cover sheets & HIRAMATSU ET AL Figure 3 Item 31); Claim 18: Wherein the sheet covers the upper openings of at least two wells including the storage well (See Jenkins et al; cover sheets & HIRAMATSU ET AL Figure 3 Item 31); Claim 20: The adhering liquid moving groove is rectangular or round in section See JENKINS ET AL Figures 3A-D & LEE ET AL, Figure 8 Item 86); Claim 21: The adhering liquid moving groove is V-shaped in section (See JENKINS ET AL Figure 3B grooves are V-shaped); Claim 22: The adhering liquid moving groove extends linearly and vertically (See JENKINS ET AL Figure 3C and LEE ET AL Figure 8); Claim 24: The adhering liquid moving groove including an upper end that contacts the closure (See HIRAMATSU ET AL Figure 3 Item 31 in view of JENKINS ET AL or LEE ET AL, where the liquid adhering moving groove can be positioned at the top of the well or is integrated to be at the top of the well); and Claim 25: The adhering

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liquid moving groove including a lower end provided below a surface of the liquid when the container contains a desired amount of the liquid (See JENKINS ET AL Figure 2, the grooves may be positioned for the intended use & Lee et al, Figure 8 Item 86).

9. Regarding Claim 23, the combination of HIRAMATSU ET AL with either JENKINS ET AL or LEE ET AL discloses the cartridge according to claim 11, except wherein the adhering liquid moving groove mover extends spirally. Both JENKINS ET AL and LEE ET AL discloses many different shapes and configurations (See JENKINS ET AL Figures 3A-D and LEE ET AL Figure 8). It would have been an obvious matter of design choice to modify the structure to be a spiral, since applicant has not disclosed that the spiral shape solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with other shapes and configurations.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over HIRAMATSU ET AL in view of JENKINS ET AL (US4847050) or LEE ET AL (US20050013746) and in further view of Okubo et al.

11. Applicants' claims are toward a device.

12. Regarding Claim 15, the combination of HIRAMATSU ET AL with either JENKINS ET AL or LEE ET AL discloses cartridge according to Claim 14, except wherein the reagent is made by dispersing an immune reactant, which reacts selectively with a specific component in a sample, in liquid as supported on solid particles. Okubo et al discloses a cartridge with this feature (See the machine English translation of JP2001318101; See Claim 9; microparticle & See [0003]). It would have been obvious

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to one or ordinary skill in the art at the time the invention was made to modify either combinations of HIRAMATSU ET AL and JENKINS ET AL or LEE ET AL, with Okubo et al, because according to Okubo et al, this immunoassay method which consists of anchoring the antibody or antigen to a substrate such as a microparticle is widely used as a measuring method with simple operation.

### ***Telephonic Inquiries***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

16. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

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automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797